

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:125. Certificate of Need annual surveys, and registration requirements for  
5 new Magnetic Resonance Imaging units.

6 RELATES TO: KRS 216B.010, 216B.020(2)(a), 216B.040

7 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the  
9 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need  
10 Program and to promulgate administrative regulations as necessary for the program.  
11 This administrative regulation establishes the requirements for registration of Magnetic  
12 Resonance Imaging units and the requirements for submission of annual survey data  
13 that are used to produce annual reports necessary for the orderly administration of the  
14 Certificate of Need Program.

15 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

16 (2) "Days" means calendar days, unless otherwise specified.

17 (3) "Exempt physicians" means physicians that operate a Magnetic Resonance  
18 Imaging unit pursuant to the exemption allowed in KRS 216B.020(2)(a).

19 (4) "Long term care facility" means any entity with licensed long term care beds  
20 including nursing facility, nursing home, intermediate care, Alzheimer's, intermediate  
21 care facility for the mentally retarded, or personal care.

1 (5) "Office of Inspector General" means the office within the Cabinet for Health and  
2 Family Services that is responsible for licensing and regulatory functions of health  
3 facilities and services.

4 (6) "Owner" means a person as defined in KRS 216B.015(21) who is applying for  
5 the certificate of need and will become the licensee of the proposed health service or  
6 facility.

7 (7) "Year" means a calendar year from January 1 through December 31.

8 Section 2. Entities Completing Surveys. The following entities shall submit annual  
9 surveys:

10 (1) Licensed Ambulatory Surgery Centers;

11 (2) Licensed Hospitals performing ambulatory surgery services or performing  
12 outpatient surgical services;

13 (3) Licensed Home Health Agencies;

14 (4) Licensed Hospice Agencies;

15 (5) Licensed Hospitals;

16 (6) Licensed Private Duty Nursing Agencies;

17 (7) Facilities with licensed long term care beds;

18 (8) Entities that hold a certificate of need for MRI equipment;

19 (9) Facilities with Megavoltage Radiation equipment;

20 (10) Licensed Psychiatric Residential Treatment Facilities; and

21 (11) Facilities with Positron Emission Tomography equipment.

22 Section 3. Entities Completing Surveys on a Voluntary Basis. Exempt physicians  
23 that have MRI equipment may submit surveys on a voluntary basis.

1 Section 4. Annual Survey Submission. Entities Completing Surveys on a Voluntary  
2 Basis. Exempt physicians that have MRI equipment shall submit surveys on a voluntary  
3 basis. An annual survey shall be completed for the previous year and transmitted  
4 electronically by accessing the Office of Health Policy's Web site at  
5 <https://prd.chfs.ky.gov/OHPSurvey/> [<http://chfs.ky.gov/ohp>].

6 Section 5. Surveys shall be submitted annually as follows:

7 (1) Kentucky Health Survey Registry 2012 Ambulatory Surgery II [~~Annual Survey of~~  
8 ~~Licensed Ambulatory Surgical Services~~];

9 (2) Kentucky Health Survey Registry 2012 Home Health II [~~Annual Survey of~~  
10 ~~Licensed Home Health Services~~];

11 (3) Kentucky Health Survey Registry 2012 Hospice [~~Annual Survey of Hospice~~  
12 ~~Providers~~];

13 (4) Kentucky Health Survey Registry 2012 Hospital Annual Survey of Licensed  
14 Hospitals;

15 (5) Kentucky Health Survey Registry 2012 Private Duty Nursing [~~Annual Survey of~~  
16 ~~Licensed Private Duty Nursing Agencies~~];

17 (6) Kentucky Health Survey Registry 2012 Long Term Care [~~Annual Survey of Long~~  
18 ~~Term Care Facilities~~];

19 (7) Kentucky Health Survey Registry 2012 Magnetic Resonance Imaging [~~Annual~~  
20 ~~Survey of Magnetic Resonance Imaging (MRI) Equipment and Services~~];

21 (8) Kentucky Health Survey Registry 2012 Megavoltage Radiation (Linear  
22 Accelerator) [~~Annual Survey of Megavoltage Radiation Services~~];

23 (9) Kentucky Health Survey Registry 2012 Psychiatric Residential Treatment Facility

1 [~~Annual Survey of Psychiatric Residential Treatment Facilities~~]; and

2 (10) Kentucky Health Survey Registry 2012 Positron Emission Tomography [~~Annual~~  
3 ~~Survey of Positron Emission Tomography (PET) Services~~].

4 Section 6. Annual surveys shall be completed and submitted no later than March  
5 15th of each year. If the 15th falls on a weekend or holiday, the submission due date  
6 shall be the next working day.

7 Section 7. Extensions for Survey Submission. (1) A request for an extension for  
8 submission of data shall be made in writing or via email to the administrator of the  
9 specific survey.

10 (2) The request for an extension shall state the facility name, survey log-in  
11 identification number, contact person, contact phone number, contact email address,  
12 and a detailed reason for the requested extension.

13 (3) One (1) extension per survey of up to ten (10) days shall be granted.

14 (4) An additional extension shall only be granted if circumstances beyond the  
15 entity's control prevents timely completion of a survey.

16 Section 8. Data Corrections to Draft Annual Reports Utilizing Data Submitted in the  
17 Annual Surveys. (1)(a) Prior to the release of draft reports to facilities for their review,  
18 the Office of Health Policy shall review data for completeness and accuracy.

19 (b) If an error is identified, the facility shall be contacted by the Office of Health  
20 Policy and allowed fourteen (14) days to make corrections.

21 (2)(a) Prior to publication of the reports, the Office of Health Policy shall publish draft  
22 reports available only to the entities included in each individual report.

23 (b) The facilities shall be notified of a website and provided with a login identification

1 and password required to access each applicable draft report and shall have fourteen  
2 (14) days to review their data for errors.

3 (c) Corrections shall be submitted in writing or via email to the Office of Health  
4 Policy before the expiration of the fourteen (14) day review period.

5 (3)(a) After publication of the reports, reports shall not be revised as a result of data  
6 reported to the Office of Health Policy incorrectly by the facility.

7 (b) Corrections received after the fourteen (14) day review period shall not be  
8 reflected in the published report.

9 (c) Facilities may provide a note in the comments section for the following year's  
10 report, referencing the mistake from the previous year.

11 Section 9. Annual Reports. (1) Utilizing data submitted in the annual surveys, the  
12 Office of Health Policy shall publish reports annually as follows:

13 (a) Kentucky Annual Ambulatory Surgical Services Report;

14 (b) Kentucky Annual Home Health Services Report;

15 (c) Kentucky Annual Hospice Services Report;

16 (d) Kentucky Annual Hospital Utilization and Services Report;

17 (e) Kentucky Annual Private Duty Nursing Agency Report;

18 (f) Kentucky Annual Long Term Care Services Report;

19 (g) Kentucky Annual Magnetic Resonance Imaging Services Report;

20 (h) Kentucky Annual Megavoltage Radiation Services Report;

21 (i) Kentucky Annual Psychiatric Residential Treatment Facility Report; and

22 (j) Kentucky Annual Positron Emission Tomography Report.

23 (2) Electronic copies of annual reports may be obtained at no cost from the Office of

1 Health Policy's Web site at <http://chfs.ky.gov/ohp>. A paper copy may be obtained for a  
2 fee of twenty (20) dollars at the Cabinet for Health and Family Services, Office of Health  
3 Policy, 275 East Main Street 4WE, Frankfort, Kentucky 40621.

4 Section 10. Any facility, other than an exempt physician that has MRI equipment,  
5 that fails to complete a required annual survey shall be referred to the Office of  
6 Inspector General for further action which may impact the facility's license renewal as  
7 provided for in 902 KAR 20:008, Section 2(6).

8 Section 11. Magnetic Resonance Imaging Equipment Registration on a Voluntary  
9 Basis by Exempt Physicians that have MRI Equipment.

10 (1) An exempt physician who uses a Magnetic Resonance Imaging unit (MRI) may  
11 register the MRI equipment by disclosing the following information by telephone contact  
12 and followed up in writing to the Cabinet for Health and Family Services:

13 (a) Name, address, and telephone number of the facility at which each unit is  
14 located or to be utilized;

15 (b) Identification of designated contact person or authorized agent of each facility;

16 (c) Make, model, and serial number of each unit;

17 (d) Date the unit became operational at each site; and

18 (e) Whether the unit is free-standing or mobile. If the unit is mobile, the submission  
19 shall also identify the number of days the unit is operational.

20 (2) Within thirty (30) days of a change in the facility's address or the addition of  
21 another MRI unit as well as the discontinuation of any units, the designated contact  
22 person or authorized agent shall notify the Office of Health Policy in writing.

23 Section 12. Incorporation by Reference. (1) The following material is incorporated by

reference:

(a) "Kentucky Health Survey Registry 2012 Ambulatory Surgery II", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Licensed Ambulatory Surgical Services", revised January 2012~~];

(b) "Kentucky Health Survey Registry 2012 Home Health II", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Licensed Home Health Services", revised January 2012~~];

(c) "Kentucky Health Survey Registry 2012 Hospice", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Hospice Providers", revised January 2012~~];

(d) "Kentucky Health Survey Registry 2012 Hospital", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Licensed Hospitals", revised January 2012~~];

(e) "Kentucky Health Survey Registry 2012 Private Duty Nursin", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Licensed Private Duty Nursing Agencies", revised January 2012~~];

(f) "Kentucky Health Survey Registry 2012 Long Term Care", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Long Term Care Facilities", revised January 2012~~];

(g) "Kentucky Health Survey Registry 2012 Magnetic Resonance Imaging", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Magnetic Resonance Imaging (MRI) Equipment and Services", revised January 2012~~];

(h) "Kentucky Health Survey Registry 2012 Megavoltage Radiation (Linear Accelerator)", screen prints dated August 23, 2012 [~~"2011 Annual Survey of Megavoltage Radiation Services", revised January 2012~~];

1 (i) "Kentucky Health Survey Registry 2012 Psychiatric Residential Treatment  
2 Facility", screen prints dated August 23, 2012 ["2011 Annual Survey of Psychiatric  
3 Residential Treatment Facilities", revised January 2012]; and

4 (j) "Kentucky Health Survey Registry 2012 Positron Emission Tomography", screen  
5 prints dated August 23, 2012 ["2011 Annual Survey of Positron Emission Tomography  
6 (PET) Services", revised January 2012].

7 (2) This material may be inspected, copied, or obtained, subject to applicable  
8 copyright law, at the Cabinet for Health and Family Services, 275 East Main Street,  
9 Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.



This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

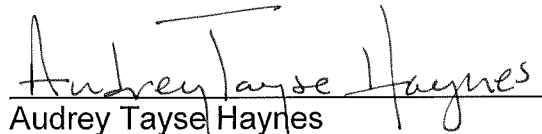
APPROVED:



Carrie Banahan  
Executive Director  
Office of Health Policy

8/28/12  
Date

APPROVED:



Audrey Tayse Haynes  
Secretary  
Cabinet for Health and Family Services

9/11/12  
Date

900 KAR 6:125

**PUBLIC HEARING AND COMMENTS:**

A public hearing on this administrative regulation shall, if requested, be held on October 22, 2012, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by October 15, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 31, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

## REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:125

Contact Person: Carrie Banahan or Chandra Venettozzi, (502) 564-9589

1. Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the requirements for completion of annual surveys with the Office of Health Policy. It also establishes voluntary registration of physician owned Magnetic Resonance Imaging (MRI) units as well as voluntary submission of annual surveys by physicians owning exempt MRI units.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010, 216B.062, 216B.990.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010, 216B.062, 216B.990 by establishing the requirements for completion of annual surveys, the voluntary registration of new Magnetic Resonance Imaging units, and voluntary completion of annual surveys by physician exempt MRI units with the Office of Health Policy for the orderly administration of the certificate of need program.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.010, 216B.062, 216B.990 by establishing the requirements for completion of annual surveys and the voluntary requirement of physician owned MRI units to register new Magnetic Resonance Imaging units or complete annual surveys with the Office of Health Policy.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: This amendment incorporates by reference the 2012 annual surveys.
- (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to provide the 2012 version of the annual surveys to entities required to submit annual surveys.

- (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by providing the 2012 version of the annual surveys.
  - (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide the 20121 version of the annual surveys.
- 3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity required to submit annual surveys and an entity wishing to voluntarily register a Magnetic Resonance Imaging unit. Approximately 800 entities complete a survey each year.
- 4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
  - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the annual survey process and MRI registration process identified in the administrative regulation are already established for all facilities, no action will be required of regulated entities to comply with this regulation.
  - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the annual survey process and the registration of MRI units identified in the administrative regulation are already established, no cost will be incurred by regulated entities to comply with this regulation.
  - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities will now have updated surveys for collection of 2012 data.
- 5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
  - (a) Initially: No cost
  - (b) On a continuing basis: No cost
- 6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used

for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. As stated above, the annual survey process and voluntary registration of MRI units identified in the administrative regulation are already used as part of our normal operations, so no additional funding will be required.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)  
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 900 KAR 6:125

Contact Person: Carrie Banahan or Chandra Venettozzi

Phone number: 502-564-9592

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010, 216B.062, 216B.990.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of annual reports. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. There is no net revenue. We anticipate that approximately 40 reports will be purchased.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of annual reports. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. There is no net revenue. We anticipate that approximately 40 reports will be purchased.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

COMMONWEALTH OF KENTUCKY  
CABINET FOR HEALTH AND FAMILY SERVICES

Office of Health Policy

900 KAR 6:125, Certificate of Need annual surveys, and registration requirements for new Magnetic Resonance Imaging units.

Summary of Changes to Material Incorporated by Reference

1. Annual surveys are required to be completed on-line. In prior years, forms that simulated the questions asked on-line were incorporated by reference with the administrative regulation. With this amendment, copies of the on-line screens used by facilities are now incorporated by reference.
2. In all surveys, references to 2011 have been revised to 2012 and references to 2012 have been revised to 2013.
3. "Kentucky Health Survey Registry 2012 Ambulatory Surgery II" is used by licensed Ambulatory Surgery Centers, Licensed hospitals performing ambulatory surgery services or performing outpatient surgical services to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 9 pages.

4. "Kentucky Health Survey Registry 2012 Home Health II" is used by licensed home health agencies to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 17 pages.

5. "Kentucky Health Survey Registry 2012 Hospice" is used by licensed hospice agencies to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 8 pages.

6. "Kentucky Health Survey Registry 2012 Hospital" is used by licensed hospitals to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 17 pages.

7. "Kentucky Health Survey Registry 2012 Private Duty Nursing" is used by licensed private duty nursing agencies to submit annual survey information. No revisions



were made to the questions asked within the survey.

The screen prints consist of 10 pages.

8. "Kentucky Health Survey Registry 2012 Long Term Care" is used by facilities with licensed long term care beds to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 10 pages.

9. "Kentucky Health Survey Registry 2012 Magnetic Resonance Imaging" is used by entities that hold a certificate of need for MRI equipment and exempt physicians that have MRI equipment to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 8 pages.

10. "Kentucky Health Survey Registry 2012 Megavoltage Radiation (Linear Accelerator)", is used by facilities with Megavoltage Radiation equipment to submit annual survey information. The following revisions were made to questions asked within the survey.

- Page 4, MEG Section – 6<sup>th</sup> paragraph - Question "Total Linear Accelerator Simulations" was changed to read "Total Simulations Performed on a Linear Accelerator"
- Page 4, MEG Section – 6<sup>th</sup> paragraph – new question added "Total Simulations performed on a CT"
- Page 4, Med Section – 6<sup>th</sup> paragraph – new question added "Total Simulations performed on another device: (Note type of device in comments)"

The screen prints consist of 6 pages.

11. "Kentucky Health Survey Registry 2012 Psychiatric Residential Treatment Facilities", is used by facilities with licensed Psychiatric Residential Treatment Facility beds to submit annual survey information. No revisions were made to the questions within the survey.

The screen prints consist of 10 pages.

12. "Kentucky Health Survey Registry 2012 Positron Emission Tomography" is used by facilities with Positron Emission Tomography equipment to submit annual survey information. No revisions were made to the questions within the survey.

The screen prints consist of 7 pages.

The total number of pages incorporated by reference is 107 pages.